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IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

THE AMERICAN LEGION,
BILL ATWELL, CAROL DELANEY-RIDOLFI,
JULIO GONZALEZ, MAREL J. MACKI,
BEVERLY NEHMER and PAUL SUTTON,
Petitioners,

v.

JESSE BROWN, SECRETARY DEPARTMENT OF VETERANS AFFAIRS; DONNA E. SHALALA, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES; DAVID SATCHER, DIRECTOR, CENTERS FOR DISEASE CONTROL; RICHARD J. JACKSON, DIRECTOR, NATIONAL CENTER FOR ENVIRONMENTAL HEALTH; UNITED STATES OF AMERICA,
Respondents.

Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

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PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

A federal statute requires the Secretary of Veterans Affairs to conduct an epidemiological study of the long term adverse health effects of exposure to Agent Orange on those Vietnam veterans who are more likely to have been exposed, and, if it finds an association between such exposure and various diseases, to provide disability and/or death compensation for Vietnam veterans suffering from such diseases. The statute requires the Secretary to conduct the study at least until after he has submitted his first report to Congress describing the "results thus far obtained under the study." The Secretary canceled the study, before collecting and reporting to Congress any health results, based on scientists' opinion that it was impossible to conduct the study in a scientifically valid manner unless the accuracy of the military records to be used in the study could be independently verified. Petitioners do not challenge respondents' inability to provide independent verification.

The questions are:

1. a. Whether, applying the traditional tools of statutory construction, Congress clearly intended that the initial "results" the Secretary was mandated by the Veterans' Health Programs Extension and Improvement Act of 1979 to report prior to being authorized to cancel the study were results as to adverse health effects, or merely whatever progress the study had made.

1. b. If Congress' intent is "ambiguous" as to statutes enacted to benefit veterans, which canon of construction is to prevail: the rule most recently announced in *Brown v. Gardner*, 115 S. Ct. 552, 555 (1994) "that interpretive doubt is to be resolved in the veteran's favor" or the rule of *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984) that courts are to defer to the agency's interpretation, if reasonable.

2. Whether a federal agency decision based solely on facts and conclusory scientists' opinion, without consideration of scientific principles or any explanation of how the agency or the scientists reasoned from the facts found to the opinion reached, is "arbitrary and capricious" under *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 167-68 (1962) and *Baltimore Gas and Electric v. Natural Resources Defense Council*, 462 U.S. 87, 103, 105-6 (1983).

TABLE OF CONTENTS

	Page
QUESTIONS PRESENTED	i
TABLE OF AUTHORITIES	v
OPINIONS BELOW	1
JURISDICTION	1
STATUTORY PROVISIONS INVOLVED	1
STATEMENT OF THE CASE	3
A. The Government's Breach Of Commitment And Injury To Vietnam Veterans Exposed To Agent Orange	3
B. The Statutory Mandate And Permissible Misclassification	5
C. Study Cancellation And The Litigation Below	9
REASONS FOR GRANTING THE PETITION	13
I. THE COURT OF APPEALS DISREGARDED THE PLAIN LANGUAGE, PURPOSE AND STRUCTURE OF THE VETERANS' HEALTH PROGRAMS EXTENSION AND IMPROVEMENT ACT OF 1979, AS WELL AS THE PLAIN LANGUAGE OF A CLOSELY RELATED STATUTE, WHICH REQUIRE THE SECRETARY TO REPORT INITIAL HEALTH RESULTS BEFORE BEING ALLOWED TO CANCEL THE STUDY	16

TABLE OF CONTENTS—Continued

Page

II. FOR RESOLVING AMBIGUITIES IN STATUTES BENEFITTING VETERANS, THE *CHEVRON* RULE REQUIRING DEFERENCE TO AN AGENCY'S REASONABLE INTERPRETATION, ON WHICH THE COURT OF APPEALS RELIED, CONFLICTS WITH THE RULE OF *BROWN v. GARDNER* THAT "INTERPRETIVE DOUBT IS TO BE RESOLVED IN THE VETERAN'S FAVOR" 21

III. UNDER THE ADMINISTRATIVE PROCEDURE ACT, AN AGENCY DECISION BASED SOLELY ON FACTS AND CONCLUSORY SCIENTISTS' OPINION, BUT FAILING TO CONSIDER RELEVANT SCIENTFIFIC PRINCIPLES AND EXPLAIN REASONING FROM THE FACTS FOUND TO THE OPINION REACHED, IS "ARBITRARY AND CAPRICIOUS" UNDER *BURLINGTON TRUCK LINES* AND *BALTIMORE GAS* 23

A. Failure To Consider Relevant Factors 23

B. Failure To Explain Rational Connection Between Facts Found And Conclusion Reached.. 29

CONCLUSION 30

APPENDIX A 1a

APPENDIX B 30a

APPENDIX C 48a

APPENDIX D 50a

APPENDIX E 51a

APPENDIX F 52a

TABLE OF AUTHORITIES

CASES: Page

Baltimore Gas and Electric v. Natural Resources Defense Council, 462 U.S. 87 (1983) 23, 29
Bethesda Hospital Association v. Bowen, 485 U.S. 399 (1988) 17
Boone v. Lightner, 319 U.S. 561 (1943) 21
Brown v. Gardner, 115 S. Ct. 552 (1994) ..... *passim*
Burlington Truck Lines, Inc. v. United States, 371 U.S. 156 (1962) 23, 29
Cardinal Chemical Co. v. Morton International, Inc., 113 S. Ct. 1967 (1993) 15
Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984) ..... *passim*
Coffy v. Republic Steel Corp., 447 U.S. 191 (1980) .. 21
Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786 (1993) 24
DeBartolo Corp. v. Florida Gulf Coast Building and Construction Trades Council, 485 U.S. 568 (1988) 22
Dole v. United Steelworkers of Am., 494 U.S. 26 (1990) 22
Esch v. Yeutter, 876 F.2d 976 (D.C. 1989) 6
Ethyl Corp. v. Environmental Protection Agency, 541 F.2d 1 (D.C. Cir. 1976) 6
Federal Trade Commission v. Anheuser-Busch, Inc., 363 U.S. 536 (1960) 18, 19
Fishgold v. Sullivan Drydock & Repair Corp., 328 U.S. 275 (1946) 21
Good Samaritan Hosp. v. Shalala, 113 S. Ct. 2151 (1993) 17
Hercules Inc. v. The United States, 24 F.3d 188 (Fed. Cir. 1994), *cert. granted*, 63 U.S.L.W. 3717 (April 3, 1995) 16
Immigration and Naturalization Services v. Cardoza-Fonseca, 480 U.S. 421 (1987) 19, 22
King v. St. Vincent's Hospital, 502 U.S. 215 (1991) 11, 22
MCI Telecommunications Corp. v. American Telephone and Telegraph, 114 S. Ct. 2223, 62 LW 4527 (1994) 17

TABLE OF AUTHORITIES—Continued

	Page
Motor Vehicle Manufacturers Association of the United States, Inc. v. State Farm Mutual Automobile Insurance Co., 463 U.S. 29 (1983)	23
New York v. United States, 342 U.S. 882 (1951)	29
Russello v. United States, 464 U.S. 16 (1983)	19
Smith v. United States, 113 S. Ct. 2050 (1993)	17
Traynor v. Turnage, 485 U.S. 535 (1988)	22
United States v. Heirs of Boisdore, 49 U.S. (8 How.) 113 (1849)	18
United States National Bank of Oregon v. Independent Insurance Agents of America, Inc., 113 S. Ct. 2173 (1993)	18
West Virginia University Hospitals, Inc. v. Casey, 499 U.S. 83 (1991)	20
STATUTES AND REGULATIONS:	
5 U.S.C. § 706(2)(A)	10
28 U.S.C. § 1254(1)	1
38 U.S.C.A. § 527 note (1991)	2
38 U.S.C.A. § 527 note § (a)(1)(A)	2, 18
38 U.S.C.A. § 527 note § (a)(2)(A)(ii)(C)	2, 8
38 U.S.C.A. § 527 note § (a)(2)(A)(i)(B)(i)	2, 8
38 U.S.C.A. § 527 note § (a)(2)(B)(ii)	2, 19
38 U.S.C.A. § 527 note § (a)(3)	2, 8, 16, 19
38 U.S.C.A. § 527 note § (b)(2)	2, 8, 16, 19
38 U.S.C.A. § 527 note § (b)(3)	3, 9, 18
38 U.S.C.A. § 527 note § (b)(4)	3, 19
38 U.S.C.A. § 527 second note § (1991)	20
38 U.S.C.A. § 527 second note § (a)(1)(B), (C)	20
38 U.S.C.A. § 527 second note § (a)(5)(A)	21
Pub. L. No. 96-151, § 307 (1979)	*passim*
Pub. L. No. 97-72, § 102(a)(1)(2) (1981)	8
Pub. L. No. 97-72, § 401 (1981)	6
Pub. L. No. 97-72, § 401(a)(2) (1981)	8
Pub. L. No. 97-72, § 401(b)(2) ¶ 4 (1981)	8
Pub. L. No. 97-72, § 401(b)(2) ¶ 3 (1981)	9
Pub. L. No. 98-160, § 601 (1983)	10, 20
Pub. L. No. 98-542, § 2(4) (1984)	20
Pub. L. No. 98-542, § 5(a)(1)(A) (1984)	9

TABLE OF AUTHORITIES—Continued

	Page
Pub. L. No. 98-542, § 8(a) (1984)	9
Pub. L. No. 102-4, § 8 (1991)	16
OTHER AUTHORITIES:	
125 Cong. Rec. S. 15180 (June 18, 1979) (Statement of Sen. Javits)	18
125 Cong. Rec. S 15178-9 (June 18, 1979) (Statement of Sen. Cranston)	18
Cong. Rec. S. 1270 (Jan. 30, 1991) (Colloquy between Senator DeConcini and Senator Daschle)	16
Cong. Rec. H. 730 (Jan. 29, 1991) (Statement of Representative Evans)	16
S. Rep. 89, 97th Cong., 1st Sess. 25-26 (May 15, 1981) (accompanying S. 921)	6
The American College Dictionary, Random House (1964)	17
The American Heritage Dictionary, Houghton Mifflin (1985)	17
Black's Law Dictionary, 1478 (4th ed. 1957)	17
2A Sutherland's Statutory Construction § 46.06 (1991 ed.)	21
U.S. Ground Troops In South Vietnam Were In Areas Sprayed With Herbicide Orange, Report by the Comptroller General of the United States, at 9 (Nov. 16, 1979)	6
Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam, Institute of Medicine, National Academy of Sciences, 27 (1994)	*passim*

PETITION FOR A WRIT OF CERTIORARI

The American Legion ("Legion"), Bill Atwell, Carol Delaney-Ridolfi, Julio Gonzalez, Marel J. Macki, Beverly Nehmer and Paul Sutton hereby petition for a writ of certiorari to review the judgment and opinion of the United States Court of Appeals for the District of Columbia Circuit, entered on April 25, 1995, in the consolidated appeals of The American Legion, Julio Gonzalez and Paul Sutton v. Jesse Brown, Secretary, Department of Veterans Affairs; Donna E. Shalala, Secretary, Department of Health and Human Services; David Satcher, Director, Centers for Disease Control; Richard J. Jackson, Director, National Center for Environmental Health; and United States of America and Bill Atwell, Carol Delaney-Ridolfi, Marel J. Macki, and Beverly Nehmer v. the same respondents.

OPINIONS BELOW

The opinion of the United States District Court for the District of Columbia granting the government's motion for summary judgment against the Legion, individual veterans and veterans' surviving spouses (App. 30a-47a)[1] is reported at 827 F. Supp. 805. The opinion of the United States Court of Appeals for the District Columbia affirming the District Court (App. 1a-27a) is reported at 54 F.3d 789.

JURISDICTION

The judgment of the court of appeals was entered on April 25, 1995. (App. 1a) On June 19, 1995, the Chief Justice extended the time for filing a petition for writ of certiorari until August 23, 1995. The jurisdiction of this Court is invoked pursuant to 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The most central provisions of section 307 of the Veterans' Health Programs Extension and Improvement

[1] All citations to "App. ——" refer to the Appendix filed contemporaneously herewith pursuant to United States Supreme Court Rule 14.1(k).

Act of 1979, as amended, 38 U.S.C.A. § 527 note (1991), provide as follows:

"(a)(1)(A) The Administrator of Veterans' Affairs shall design a protocol for and conduct an epidemiological study of any long-term adverse health effects in humans of service in the Armed Forces of the United States in the Republic of Vietnam during the period of the Vietnam conflict as such health effects may result from exposure to phenoxy herbicides (including the herbicide known as Agent Orange) and the class of chemicals known as the dioxins produced during the manufacture of such herbicides.

* * * *

"(2)(A)(i) The study conducted pursuant to paragraph (1) shall be conducted in accordance with a protocol approved by the Director of the Office of Technology Assessment.

"(ii) The Director shall monitor the conduct of such study in order to assure compliance with such protocol.

"(B)(i) Concurrent with the approval or disapproval of any protocol under subparagraph (A)(i), the Director of the Office of Technology Assessment shall submit to the appropriate committees of the Congress a report explaining the basis for the Director's action in approving or disapproving such protocol and providing the Director's conclusions regarding the scientific validity and objectivity of such protocol.

* * * *

"(3) The study conducted pursuant to paragraph (1) shall be continued for as long after the submission of the first report under subsection (b)(2) as the Administrator may determine reasonable in light of the possibility of developing through such study significant new information on the long-term adverse health effects of exposure to dioxins.

* * * *

"(b)(2) Not later than twenty-four months after the date of the approval of the protocol pursuant to

subsection (a)(2)(A)(i) and annually thereafter, the Administrator shall submit to the appropriate committees of the Congress a report containing (A) a description of the results thus far obtained under the study conducted pursuant to such subsection, and (B) such comments and recommendations for administrative or legislative action, or both, as the Administrator considers appropriate in light of such results.

"(3) Immediately after the submission of each report under paragraph (2), the Administrator, based on the results described in such report and the comments and recommendations included therein and any other available pertinent information, shall evaluate the need for any amendments to regulations, prescribed pursuant to section 5 of the Veterans' Dioxin and Radiation Exposure Compensation Standards Act, [section 5 of Pub.L. 98-542, set out as a note under section 1154 of this title] for the resolution of claims for service connection based on the exposure specified in subsection (a)(1)(A) of such section. . . .

"(4) The first report submitted under paragraph (2) shall include the Administrator's recommendation, and reasons therefor, with respect to whether the authority to provide care and services under and by virtue of section 610(a)(5) of title 38, United States Code [now section 1710(a)(5) of this title], should be extended beyond the expiration period specified by section 610(e)(3) of such title [now section 1710(e)(3) of this title]."

* * * *

STATEMENT OF THE CASE

A. The Government's Breach Of Commitment And Injury To Vietnam Veterans Exposed To Agent Orange

In 1979 Congress initiated, and in 1981 and 1984, renewed, two solemn promises to tens of thousands [2] of sick Vietnam veterans. In the Veterans' Health Programs

[2] For precise numbers over time, see Reasons for Granting the Petition, p. 13, *infra*.

Extension and Improvement Act of 1979, Pub. L. No. 96-151, § 307, 93 Stat. 1092, 38 U.S.C.A. § 527 note (1991) (as amended) (the Act) Congress mandated: first, that the Government would conduct an epidemiological study of whether any of the cancers and other diseases Vietnam veterans suffered were borne disproportionately by those who were more likely to have been exposed to Agent Orange [3] or other defoliant herbicides containing dioxin which the Government had sprayed in Vietnam; and second, that the Government would pay disability compensation to Vietnam veterans for, and death benefits to their families for any veterans' deaths resulting from, any diseases found to be associated with such exposures. This case challenges the Government's breach of those solemn commitments.

Instead of conducting the mandated epidemiological study, in 1988, the then Administrator of Veterans Affairs (now the Secretary)[4] cancelled it. He did so before ever collecting, from physical examinations and health histories of the study subjects, Jt. App. 109F-114,[5] any information on adverse health effects. Because of the cancellation, hundreds of thousands of Vietnam veterans have been prevented from learning whether diseases they have suffered, and, for many, died from, were associated with likely exposure to the herbicides' toxic chemical dioxin.[6] And they, and their families, have been deprived

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[3] Agent Orange was the principal herbicide sprayed in Vietnam and accounted for virtually all of the herbicide sprayed containing dioxin. *Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam,* Institute of Medicine, National Academy of Sciences, 27, 87, 91 (National Academy Press, 1994) (NAS Report).

[4] See App. 2a, n.1.

[5] All citations to "Jt. App. ——" refer to the Joint Appendix filed in the proceedings before the United States Court of Appeals for the District of Columbia Circuit.

[6] Dioxin is a highly toxic chemical, 2, 3, 7, 8-tetrachlorodibenzo-p-dioxin (TCDD), produced as an unintended by-product in manufacturing Agent Orange and other herbicides which together accounted for about 60% of the herbicides sprayed in Vietnam. See NAS Report at 27, 89, 97-98.

of VA disability and/or death compensation which would have been provided if the study had revealed such results.

Petitioners (the veterans) know those losses intimately. The American Legion, a congressionally-chartered, non-profit, veterans service organization has approximately 3 million members, including about 1 million Vietnam-era veterans. Many of these Legion members were exposed to herbicides containing dioxin during the Vietnam War. They believe the cancers and other serious diseases they have contracted are due to that exposure. They have sought service-connected disability compensation from the Department of Veterans Affairs (VA) but have been denied because of inadequate scientific evidence linking their adverse health effects with exposure.

Individual petitioners Julio Gonzalez and Bill Atwell are Vietnam veterans who developed serious diseases, including bladder cancer and kidney cancer, respectively, after exposure to phenoxy herbicides, *i.e.*, herbicides containing dioxin, in Vietnam. Petitioner Paul L. Sutton is a former Marine who served two tours in Vietnam and, after exposure to phenoxy herbicides in Vietnam, fathered three children with severe birth defects. Petitioners Marel J. Macki, Beverly Nehmer and Carol Delaney-Ridolfi are the surviving spouses of Vietnam veterans who died from malignant melanoma and brain cancer, leukemia, and acute myoblastic leukemia, respectively, after exposure to phenoxy herbicides in Vietnam.

B. The Statutory Mandate And Permissible Misclassification

Pub. L. 96-151 grew from Congress' recognition in the late 1970's that a large number of Vietnam veterans, people in their 20's and 30's, who believed they had been exposed to Agent Orange, were beginning to contract cancers and other serious diseases, as well as produce children with birth defects. The law was enacted within five weeks after the Comptroller General published a report that sufficient military records of ground troops and

herbicide spray location existed to estimate which ground units were most likely to have been exposed to Agent Orange. The Comptroller recommended that Congress direct various government agencies to determine whether a study was needed of "the health effects of herbicide orange on ground troops." [7]

Originally, in 1979, Congress required VA to "conduct an epidemiological study [8] of [veterans] who *were exposed* to dioxins. . . .", Pub. L. 96-151, § 307(a)(1) (Emphasis added) Congress thereby implied its belief that the military records were, in general, sufficiently detailed to determine which individual veterans had actually been exposed. But, by 1981, Congress recognized that this premise was false, and that its statutory restriction of study subjects to veterans who "were exposed" had prevented starting the study of adverse health effects. S. Rep. 89, 97th Cong., 1st Sess. 25-26 (May 15, 1981) (accompanying S. 921, the basis for Pub. L. 97-72, 95 Stat. 1061 (Nov. 3, 1981)). Thus, in 1981, to enable the health study to proceed, *id.*, Congress repealed the restrictive "were exposed" requirement. Instead, Congress substituted the more permissive requirement that VA need study merely health effects which "*may result from exposure. . . .*" (Emphasis added) Pub. L. 97-72, § 401, 95 Stat. 1061 (Nov. 3, 1981).

In January 1983, VA contracted with the federal government's Centers for Disease Control (CDC) to develop

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[7] "U.S. Ground Troops In South Vietnam Were In Areas Sprayed With Herbicide Orange", Report by the Comptroller General of the United States, at 9 (Nov. 16, 1979). Petitioners believe that this report is admissible as containing important background and technical information, *see Esch v. Yeutter*, 876 F.2d 976, 991-992 (D.C. Cir. 1989), and a copy is lodged with the Clerk's Office.

[8] "Epidemiologists study the effects of various phenomena on humans under uncontrolled or 'natural' conditions. These effects are correlated with other observed facts in an attempt to develop significant relationships among the data. The science is limited, however, in that inferences may be drawn, but relationships cannot be proved by the correlations alone." *Ethyl Corp. v. Environmental Protection Agency*, 541 F.2d 1, 42 (D.C. Cir. 1976).

a "protocol" (design) for, and conduct, the study. Jt. App. 162. From the outset, CDC recognized that because the military records generally could not identify which individual veterans definitely had or had not been exposed, it would instead have to distinguish between groups of veterans based on the groups' respective likelihoods of exposure. See Jt. App. 102-103, 114C. For the same reason, CDC acknowledged that there was a risk of "misclassification," *i.e.*, some individual veterans who had not, in fact, been exposed might be included in the "likely exposed" cohort (group), and others who actually had been exposed might be in the "likely not exposed" cohort. See Jt. App. 103, 107, 114B-C, 114L.

In the science of epidemiology there are ways to protect against and counteract measurement error from misclassification. Jt. App. 303-305. Indeed, CDC designed the study with this in mind to include not only two cohorts, one "likely exposed" and one "likely not exposed," both from a sector of Vietnam which had heavy spraying in it, but also a third cohort from another sector "where there is good evidence of little or no herbicide usage." Jt. App. 103, 107.

Moreover, CDC recognized that in epidemiology random misclassification does not *per se* render a study scientifically invalid, even if the actual misclassification is "sizeable." Jt. App. 114C, 195-96. What such misclassification does is to make it harder to detect the real increased risks of adverse health effects from exposure, and thereby to underestimate whether, and, if so, to what extent, certain diseases correlated with exposure. Jt. App. 114B-114C, 195-96. As CDC noted with respect to this study, notwithstanding random misclassification, "[i]f health effects are strong enough, they would be discovered in the study, albeit underestimated." Jt. App. 196.

CDC did not believe that its study needed to, nor could, confidently identify cohorts whose differences in exposure were " 'meaningful' [in the sense that they] might a priori

be considered enough to result in differences in long-term health. . . ." Jt. App. 194. CDC's goals for the study were modest: "CDC believes only that its sampling plan should identify groups of men who will differ to some degree in their accumulated exposure." *Id.*

In July 1983, the Office of Technology Assessment (OTA), which Congress had charged to review the study protocol for "scientific validity and objectivity", Pub. L. 96-151, § 307(a)(2)(A)(i), (B)(i) (1979), 38 U.S.C.A. § 507 note § (a)(2)(A)(i), (B)(i), and approve it before the study could be begun, *id.*, approved CDC's protocol.[9] VA (through CDC) was statutorily obligated to carry out the study according to the approved protocol, Pub. L. 96-151, § 307(a)(2)(A)(ii)(C) (1979), 38 U.S.C.A. § 527 note § (a)(2)(A)(ii) (C). The Secretary was not authorized to cancel the study until after he had submitted to Congress his "first" report, Pub. L. 97-72, § 401(a)(2) (Nov. 3, 1981), 38 U.S.C.A. § 527 note § (a)(3), describing the "results thus far obtained under the study." Pub. L. 96-151, § 307(b)(2), 38 U.S.C.A. § 527 note § (b)(2).

Congress contemplated that those results would enable it to determine whether to continue to authorize VA hospital and nursing home care for Vietnam veterans who "may have been exposed during . . . service to dioxin", Pub. L. 97-72, § 401(b)(2) ¶ 4 (1981) with Pub. L. 97-72, § 102(a)(1) (2) (1981), as well as implicitly to

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[9] In its approval letter, OTA noted that: "Given the imperative to execute those studies [one of which was the study at issue], the CDC protocols provide an appropriate general construct that it is not likely to be improved upon . . . Congress, in mandating the study, is seeking to provide answers to questions that plague veterans and their families; the available records enable the study to be undertaken but the limited quality of those records (sic) also probably limits the accuracy of the answers that can be expected." Letter from John H. Gibbons to Honorable Harry N. Walters, Administrator, Veterans Administration, July 8, 1983. Petitioners believe that this letter is admissible per footnote 9. The Clerk's Office has a copy.

allow the VA administrator to determine for which diseases he should grant compensation based on presumptive Agent Orange exposure. Pub. L. 97-72, § 401(b)(2) ¶ 3 (1981). In October 1984, Congress amended Pub. L. 96-151 to make explicit that, based on the "results" obtained pursuant to Pub. L. 96-151, § 307(b)(2), the Administrator was to grant service-connected compensation to veterans for any diseases for which the study revealed association with exposure to dioxin. See Pub. L. 98-542, § 8(a) (Oct. 24, 1984) with Pub. L. 98-542, § 5(a)(1)(A), 38 U.S.C.A. § 527 note, § (b)(3).

C. Study Cancellation And The Litigation Below

On February 9, 1988, the Secretary, after receiving several reports and recommendations, decided to cancel the study. He determined that no "scientifically sound study can be undertaken," Jt. App. 262, because, as construed by the Court of Appeals, misclassification made it "impossible to determine whether a particular group of veterans is more likely to have been exposed to Agent Orange and other herbicides than a comparable cohort of their peers." App. 25a. The cancellation decision was based essentially on two conclusions: 1) the risk of misclassification in the military records was so great that it would destroy the scientific validity of the study, see App. 22a-25a, unless the accuracy of the military records in distinguishing between exposed and unexposed veterans could be independently verified, App. 23a-25a and n.16; and 2) no method existed to independently verify the records' accuracy. App. 23a-24a.

In 1990, The American Legion and various individual petitioners filed two separate actions in the United States District Court for the District of Columbia.[10] See App. 24, 27. They sought to require the VA to conduct the cancelled Agent Orange exposure study and grant service-connected disability compensation to Vietnam veterans

[10] The actions were subsequently consolidated in the district court and remained so on appeal. See App. 1a, 30a.

for, and death compensation to their survivors for veterans' deaths resulting from, any diseases which would be warranted by the study's results. The veterans presented several claims that respondents' study cancellation violated Pub. L. 96-151, as amended, and was therefore "not in accordance with law" under the Administrative Procedure Act (APA), 5 U.S.C. § 706(2)(A), as well as several claims that the cancellation was "arbitrary and capricious" under the same section. See generally App. 43a-47a.

The district court denied the Government's motion to dismiss, App. 36a, n.6, tacitly agreed with the veterans that if the White House Domestic Policy Council's cancellation of the study had been the final decision to cancel, it would have been illegal, App. 38a-40a and nn.9-10, and rejected the Government's argument that it was entitled to summary judgment based on Congress' purported ratification by appropriation of the cancellation decision. App. 36a-37a. However, the district court granted the Government summary judgment on the merits. App. 47a.

In the United States Court of Appeals for the District of Columbia Circuit, the veterans raised two issues relevant to this petition.[11] First, they argued that the Act's purpose, language and structure, as well as the language of the closely related 1983 radiation exposure study statute, Pub. L. 98-160, § 601, 87 Stat. 1006, 38 U.S.C.A. § 527 second note (1991) (as amended), revealed that Congress clearly intended that the "results" the Secretary had to report before he could cancel the study were health results, not merely progress. Since the Secretary indisputably cancelled the study before gathering any health results, the cancellation was contrary to law.

The D.C. Circuit rejected this argument. Instead, the Court of Appeals held that it was not clear whether Congress intended to require the Secretary to report health

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[11] Petitioners are not pursuing in this Court their argument that the Secretary applied the repealed "were exposed" standard of the 1979 statute. See App. 18a-22a.

effects or merely "progress" before he could cancel the study. App. 13a-17a. Therefore, under *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 841-42 (1984), the Circuit held it "must defer to the Secretary's interpretation" that he only needed to submit a progress report to Congress prior to cancellation, since the court believed that the Secretary's interpretation was permissible. App. 14a.

But in so ruling the Court of Appeals wholly failed to consider, let alone apply, this Court's longstanding principle that ambiguous language in statutes for the benefit of veterans must be construed favorably to the veterans. In *Brown v. Gardner*, 115 S. Ct. 552, 555 (1994), this Court most recently noted the "rule that interpretative doubt is to be resolved in the veteran's favor . . . ."; *accord, e.g. King v. St. Vincent's Hospital*, 502 U.S. 215, 220 n.9 (1991).

The Court of Appeals held, in effect, alternatively, that even if the veterans were correct that the "traditional tools of statutory construction" showed Congress clearly intended "results" to be health effects, that construction must be rejected here because it would lead to the purportedly "absurd results" that the Secretary would have to conduct a study he had determined could not be scientifically valid. App. 14a, 17a, n.13, 17a-18a. The appeals court recognized, however, that reading the Act to require the Secretary to conduct the study would only be "absurd" if it were "[a]ssum[ed]" that the Secretary's conclusion that it was impossible to do a scientifically valid study was "accura[te]." App. 18a.

The veterans' second issue challenged not just the "accuracy" of the Secretary's conclusion that it was impossible to do a "valid" study with military records without independent verification, but its fundamental "rationality." Petitioners did not dispute that *if* the Secretary had rationally concluded that military records alone could not produce a valid study unless their accuracy were independently verified, then the veterans' claims would fail because

independent verification was not available.[12] Rather, petitioners argued that the Secretary's threshold determination that military records were not adequate for a scientifically valid study unless their accuracy had been independently verified was itself "arbitrary and capricious." Thus, the Secretary had no rational basis for having refused to do the military records study regardless of his inability independently to have verified their accuracy.

Initially, the veterans argued that the sole basis in the record for the Secretary's conclusion that the risk of misclassification was so great that the military records could not produce a scientifically valid study unless their accuracy was independently verified was the "feelings" of the Science Subpanel. Jt. App. 46. Respondents had presented no scientific principles for judging when misclassification risk becomes so great that it destroys a study's scientific validity. Reliance on scientists' mere conclusory opinion, without any foundation in scientific methodology, the veterans argued, was "arbitrary and capricious". The Appeals Court responded that the Secretary's conclusion that the military records could not generate a valid study unless separately verified rested not only on the Subpanel's "feelings", but also on three opinions or findings from other scientific groups. App. 24a-25a, n.16.

Finally, the veterans argued that the Secretary's conclusion that the risk of misclassification was so great that it prevented the study from being scientifically valid unless the military records' accuracy was independently verified was "arbitrary and capricious" because the Secretary failed to provide any reasoned explanation for why the degree of misclassification risk the Subpanel perceived exceeded the maximum permitted for a study to be

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[12] Thus, the Court of Appeals misconceived the veterans' argument when it asserted that "the question in these appeals is whether the Secretary had a rational basis for determining that no known method existed to verify whether the military records based assessments differentiated between exposed and non-exposed veterans in the way necessary for a cohort study." App. 24a.

scientifically valid. The veterans did not dispute the Subpanel's assessment of the degree of risk of misclassification,[13] *i.e.*, that "[t]he combined effect of these two sources of misclassification is unclear, but undoubtedly they would seriously bias measures of effect toward the null and greatly reduce study power." Jt. App. 46. (That is, misclassification would make it much harder to identify the adverse effects due to herbicide exposure.) Instead, the veterans challenged the fact that neither the Secretary nor the experts on whom he relied explained why that degree of misclassification would destroy the study's validity, rather than merely make it harder for the study to detect true adverse effects from exposure. The Court of Appeals never addressed this argument.

REASONS FOR GRANTING THE PETITION

The number of people injured by the Secretary's challenged decision to cancel the Agent Orange exposure study is huge. In 1978-1980 alone, 33,156[14] Vietnam veterans expressed concern to VA that their exposure to herbicides in Vietnam may be causing them adverse health effects, and were accordingly given VA's Agent Orange health examination and listed on VA's Agent Orange Registry. Many of the diseases which the veterans suffered were cancers which are believed to have a long latency period.[15] Today, as more Vietnam veterans have become sick, the number on the Registry has catapulted to 245,162.

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[13] Accordingly, the appeals court misconceived the veterans' argument when it said that "appellants charge the Secretary should have . . . determine[d] . . . the degree of misclassification. . . ." App. 25a.

[14] This and the succeeding number of individuals on the Agent Orange Registry were provided telephonically to counsel's office by the Environmental Agents Service, VA's Office of Public Health and Environmental Hazards (Aug. 1-4, 1995).

[15] NAS Report at 435.

Moreover, the number of people harmed by the VA's refusal to conduct the study is not only the veterans themselves, but also their families, each of whom is potentially being deprived of thousands of dollars per year of VA disability compensation which their veteran predictably would have been receiving if the study had found the veteran's disease associated with herbicide exposure.[16] Perhaps most tragically, when a veteran dies prematurely of diseases which may have been due to Agent Orange exposure, the spouse and children are being deprived of death benefits to which they otherwise might have been entitled.

Against the possibility that tens or hundreds of thousands of veterans and their families might benefit from having the statutorily mandated study conducted, the only justification the Secretary has offered for refusing to do the study boils down to his concern that misclassification will "seriously bias measures of effect toward the null and greatly reduce study power". Jt. App. 46. Taking the Secretary's concern to its logical limit, the misclassification might be so serious that the study would not be able to identify any adverse health effects associated with herbicide exposure, even if in fact such associations exist. Jt. App. 287.

But whether the study would in fact fail to find any associations between exposure and any diseases cannot be known in advance. The mere possibility that it might turn out to be unproductive pales in comparison to the possibility it might succeed in identifying diseases associated with Agent Orange. As CDC said, if the associations are strong enough, they will be detected even if there is a high degree of random misclassification. Jt. App. 196.

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[16] Conservatively, multiplying the number of veterans on the Registry by 2.5 (less than the 2.63 average number of persons per American household as of March 1993 reported by the Census Bureau), the maximum number of individuals potentially injured may be estimated at 612,905.

While other epidemiological studies have been done of Vietnam veterans based solely on service in Vietnam,[17] and a small scale Agent Orange exposure study has been done of veterans associated with spraying the herbicides from fixed wing aircraft [18], none has served the essential and unique function which the cancelled Agent Orange exposure study was to serve: to assess the adverse health effects of likely exposure to herbicides on the vast majority of Vietnam veterans who were exposed to herbicides—the ground combat troops. This is the missing, central piece of the puzzle. Without it, there would never be any direct information as to what, if any, health effects were associated with exposures experienced by the ground forces who fought in the jungles and other heavily vegetated areas where the herbicides were sprayed.

This is a nationwide suit. It challenges a single agency action that has had nationwide effect. It is brought by a national veterans service organization including approximately 1 million Vietnam veterans throughout the country, which serves all veterans who request assistance. While there is no conflict in the circuits, as a practical matter this case is similar to a nationwide class action in which there would never be a conflict. Here, because of the nationwide character of the suit, and the time and expense of pursuing it, unless this Court grants certiorari now, it predictably would never have another chance to consider these issues based on a conflict in the circuits, because it is virtually inconceivable that any other suit to enforce Pub. L. 96-151 would ever be brought.[19]

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[17] See Vietnam Experience Study, Jt. App. 104; NAS Report at 389-391 and Selected Cancer Study, Jt. App. 104-5; NAS Report at 391-393.

[18] See "Ranch Hand" Study, NAS Report at 385-386.

[19] As with important decisions of nationwide effect from the United States Court of Appeals for the Federal Circuit, notwithstanding the absence of a conflict in the circuits, the decision of the D.C. Circuit below raises "a matter of special importance to the entire Nation." *Cardinal Chemical Co. v. Morton International,*

In the legislative history to the Agent Orange Act of 1991, Pub. L. 102-4 (Feb. 6, 1991), 105 Stat. 11, 38 U.S.C. § 1116 (1993), Congress itself recognized that this suit was pending challenging the cancellation of the study mandated by Pub. L. 96-151 and that that law remained in effect.[20] Only if the Act is enforced to require the VA to conduct the study will the hundreds of thousands of affected Vietnam veterans and their surviving spouses be given the chance Congress intended that it might produce the evidence needed to entitle them to VA disability and death compensation.

I. THE COURT OF APPEALS DISREGARDED THE PLAIN LANGUAGE, PURPOSE, AND STRUCTURE OF THE VETERANS' HEALTH PROGRAMS EXTENSION AND IMPROVEMENT ACT OF 1979, AS WELL AS THE PLAIN LANGUAGE OF A CLOSELY RELATED STATUTE, WHICH REQUIRE THE SECRETARY TO REPORT INITIAL HEALTH RESULTS BEFORE BEING ALLOWED TO CANCEL THE STUDY

It is conceded that the Act's language does not authorize the Secretary to cancel the study until "after the submission [to Congress] of the first report," 38 U.S.C.A. § 527 note § (a)(3), which describes "the results thus far obtained under the study." 38 U.S.C.A. § 527 note § (b)(2). Petitioners contend that the Act's language, purpose and structure, reinforced by the language of the closely related radiation exposure study statute, reveal that Congress clearly intended that the initial study "results" the Secretary had to report before he could cancel

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Inc., 113 S. Ct. 1967, 1971 (1993). Indeed, this Court has very recently recognized the appropriateness, absent circuit conflict, of granting review of cases involving important interests of veterans, *Gardner*, 115 S. Ct. 552, and Agent Orange. *Hercules Inc. v. The United States*, 24 F.3d 188 (Fed. Cir. 1994), *cert. granted*, 63 U.S.L.W. 3717 (April 3, 1995).

[20] Cong. Rec. S. 1270 (Jan. 30, 1991) (colloquy between Senator DeConcini and Senator Daschle); Cong. Rec. H. 730 (Jan. 29, 1991) (Statement of Representative Evans).

were results as to adverse health effects. The Court of Appeals, in straining to avoid this obvious conclusion by finding that Congress equally could have intended to require only a "progress" report, disregarded basic principles of statutory construction.

Although this Court has recognized that "[t]he starting point in interpreting a statute is its language," *Good Samaritan Hosp. v. Shalala,* 113 S. Ct. 2151, 2157 (1993), and the place to begin assessing the ordinary meaning of statutory language is the "dictionary," *e.g., MCI Telecommunications Corp. v. American Telephone and Telegraph*, 114 S. Ct. 2223, 2229 (1994); *Smith v. United States*, 113 S. Ct. 2050, 2054 (1993), the Court of Appeals avoided dictionaries. Instead, it relied solely on "common parlance" to conclude that " 'results' is . . . subject to multiple meanings." App. 14a. But this is too facile.

The dictionary definitions of "results" and "progress" are significantly different. "Result" denotes the final product or conclusion of a process, whereas "progress" signifies merely moving forward toward an end. "Result" is defined as: "that which results; the outcome, consequence or effect", *The American College Dictionary,* Random House, 1035 (1964); "the conclusion or end to which any course or condition of thing leads, or which is obtained by any process or operation." Black's Law Dictionary, 1478 (4th ed. 1957). By contrast, "progress" is defined as: "forward or onward movement in space or course"; *The American College Dictionary,* Random House, 967 (1964); "movement toward a goal." The American Heritage Dictionary, 2nd College Ed., Houghton Mifflin 990 (1985). To construe "results", the end of a process, as intended to mean merely interim steps taken in a process, is to rip "results" from its mooring. *See Bethesda Hospital Association v. Bowen*, 485 U.S. 399, 404 (1988).

While this Court has repeatedly emphasized that courts must interpret a statute in light of its "object and policy,"

United States National Bank of Oregon v. Independent Insurance Agents of America, Inc., 113 S. Ct. 2173, 2182 (1993), quoting *United States v. Heirs of Boisdore*, 49 U.S. (8 How.) 113, 122 (1849), its "purpose", *Federal Trade Commission v. Anheuser-Bush, Inc.*, 363 U.S. 536, 546 (1960), the Court of Appeals here failed to address the Act's purpose, or how it bore on the intended meaning of "results." The answer is manifest both on the face of the statute and in its legislative history.

The legislative history shows that the Act was a response to the facts that: the public recognized that dioxin contained in Agent Orange and other herbicides sprayed in Vietnam was a highly toxic substance, 125 Cong. Rec. 15180 (June 18, 1979) (Statement of Sen. Javits), 125 Cong. Rec. 15178-79 (June 18, 1979) (Statement of Sen. Cranston); significant numbers of Vietnam veterans were seeking VA service-connected disability compensation for cancers and other serious diseases they believed were associated with exposure to dioxin in Vietnam, but VA was denying all the claims except for one skin condition, chloracne, 125 Cong. Rec. 15179 (June 18, 1979) (Statement of Sen. Cranston); no large scale epidemiologic studies had been done to enable the government to distinguish which diseases may have been due to dioxin exposure from those which were probably not, 125 Cong. Rec. 15179 (June 18, 1979) (Statement of Sen. Cranston), 125 Cong. Rec. 15180 (June 18, 1979) (Statement of Sen. Javits); and the "VA ha[d] shown an inexcusable lack of priority for this study." 125 Cong. Rec. 15180 (June 18, 1979) (Sen. Cranston).

The Act's purpose was to ensure that the Government, by conducting an epidemiological study, would learn whether Vietnam veterans who had a greater likelihood of having been exposed to phenoxy herbicides had a higher incidence of certain diseases, 38 U.S.C.A. § 527 note, § (a)(1)(A), so that if so, VA could grant presumptive service-connected disability and death compensation for such diseases, 38 U.S.C.A. § 527 note,

§ (b)(3), and Congress could continue to authorize VA hospital and nursing home care to treat them. 38 U.S.C.A. § 527 note, § (b)(4).

How the statutory purpose bore on what Congress intended by requiring an initial report of "results" before the study could be canceled is readily apparent: the only way Congress' purposes could be achieved was if VA reported to it health results before it cancelled the study. Indeed, the Court of Appeals concedes that Congress never even considered the possibility that the study might be cancelled before it "yield[ed] substantive health results." App. 17a, n.13. Just as in *Anheuser-Bush, Inc.*, 363 U.S. at 546, "the incompatibility of the Circuit Court's [construction] with the purpose of [the Act]" is fatal.

And the Court of Appeals' analyses of structure are similarly flawed. That Congress required "update" reports for protocol approval, § (a)(2)(B)(ii), prior to conducting the study, whereas it specified "results" reports for the study itself, § (a)(3), (b)(2), App. 16a, in no way undermines the principle that Congress' use of different words implies it intended different meanings. *See Immigration and Naturalization Serv. v. Cardoza- Fonseca*, 480 U.S. 421, 432 (1987), quoting *Russello v. United States*, 464 U.S. 16, 23 (1983), (" 'where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.' ") Had Congress intended to require that VA need only make an "update" report before cancellation, it would have said so.

Nor does the Court of Appeals face the fact that by reading the Act as if Congress had written that the Secretary could cancel the study after one "progress" report, rather than one report of "results", it has effectively nullified the difference between the restrictive cancellation scheme in the Act and the far more permissive cancellation scheme in the analogous radiation exposure study

law, the Veterans Health Care Amendments of 1983, Pub. L. 98-160, § 601, 97 Stat. 1006-08 (1983), 38 U.S.C. § 527 second note (as amended). App. 16a-17a. *See Gardner*, 115 S. Ct. at 555 (Court analyzes analogous statutes as one of its tools of statutory construction). The radiation statute, unlike Pub. L. 95-151, does not require OTA approval of VA's protocol as a prerequisite to conducting the study, nor VA implementation in compliance with an approved protocol. Moreover, it expressly authorizes Secretarial cancellation of the radiation study at any time the Secretary determines, after consulting OTA, that it cannot be done in a scientifically valid manner, and the Secretary so notifies Congress. 38 U.S.C. § 527 second note § (a)(1)(B), (C).

Since, as a practical matter, the mere requirement to submit a "progress" report as a prerequisite to cancellation in no way constrains the Secretary's discretion as to when to cancel, the Circuit Court has eviscerated the Agent Orange statute to the point that it confers as much cancellation discretion on the Secretary as the radiation statute, even though the language of Pub. L. 96-151's cancellation scheme is much more restrictive. This is impermissible. *E.g.*, *West Virginia University Hospitals, Inc. v. Casey*, 499 U.S. 83, 99 (1991).[21]

Finally, the Circuit Court's assertion that the fact that the radiation statute requires the Secretary to report to Congress "a description of the *progress on and any re-*

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[21] Indeed, in 1984, Congress itself expressly repudiated the appeals court's view that Pub. L. 96-151 conferred as much discretion on the Secretary to cancel the dioxin study as to cancel the radiation study when Congress noted that Congress "requir[ed] . . . the conduct of thorough epidemiological studies of the health effects experienced by veterans in connection with exposure both to herbicides containing dioxin and (if not determined to be scientifically infeasible) to radiation, ..." Pub. L. 98-542, § 2(4) (Oct. 24, 1984), 98 Stat. 2725. Thus, Congress understood that after OTA protocol approval, the duty to conduct the dioxin study was categorical, whereas the radiation study could be cancelled at any time the Secretary determined invalidity.

sults under such [radiation exposure] study," 38 U.S.C.A. § 527 second note, § (a)(5)(A) is not "inconsistent" with construing "results" in the Act to mean "progress" report, App. 17a, is indefensible. (Emphasis added) It is fundamental that all words in a statute are to be construed to have a separate meaning so that none is rendered superfluous. 2A Sutherland's Statutory Construction § 46.06 (5th ed. 1991). Congress knew exactly the difference between requiring a report of a study's "progress" and its "results." Neither word is superfluous and they are not equivalent. The Court of Appeals' holding that the congressionally intended meaning of "results" was "ambiguous", and therefore necessitated proceeding to *Chevron*'s step two, is unwarranted.

II. FOR RESOLVING AMBIGUITIES IN STATUTES BENEFITTING VETERANS, THE *CHEVRON* RULE REQUIRING DEFERENCE TO AN AGENCY'S REASONABLE INTERPRETATION, ON WHICH THE COURT OF APPEALS RELIED, CONFLICTS WITH THE RULE OF *BROWN v. GARDNER* THAT "INTERPRETIVE DOUBT IS TO BE RESOLVED IN THE VETERAN'S FAVOR"

This case presents a sharp conflict between two of this Court's rules of statutory construction. By invoking the rule of *Chevron* deference, the Court of Appeals wholly disregarded this Court's more narrow rule, most recently announced in *Gardner*, that for ambiguities in veterans benefits statutes, "interpretive doubt is to be resolved in the veteran's favor." 115 S. Ct. at 555. That rule grows out of the special debt the nation has to those who have sacrificed to protect her, and originated at least as far back as *Boone v. Lightner*, 319 U.S. 561, 575 (1943) and *Fishgold v. Sullivan Drydock & Repair Corp.*, 328 U.S. 275, 285 (1946). This rule has been endorsed more recently not only in *Gardner*, but in *Coffy v. Republic Steel Corp.*, 447 U.S. 191, 196 (1980) and *St. Vincent's Hospital*, 502 U.S. at 221 n.9.

Since the Veteran's Health Programs Extension and Improvement Act of 1979 at issue here was enacted to

benefit veterans, it is the type of statute to which the *Gardner* rule applies. Veterans could only gain VA compensation from the Act if the study is performed at least to the stage of gathering initial health results. Thus, for "interpretive doubt . . . to [be] resolved in the veteran's favor" would require construing "results" as health results, so that the cancellation would have been illegal and the study would have to be done. This is, of course, the exact opposite of what would have been required under *Chevron*, assuming that respondents' interpretation was permissible. On the facts of this case, therefore, the two canons of construction are in irreconcilable conflict.

The *Gardner* canon of construction might operate at step one of *Chevron*, so that potential ambiguity would be eliminated before ever reaching step two. This would be similar to *Gardner*'s reliance on the canons that "a given term is used to mean the same thing throughout a statute," 115 S. Ct. at 555, and that "it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion [of particular language]", *id.*, at 556, to support its *Chevron* step one conclusion that "the text and reasonable inferences from it give a clear answer against the Government, ..." *Id.* Accord, *Dole v. United Steelworkers of Am.*, 494 U.S. 26, 36, 42-43 and n.10 (1990); *Cardoza-Fonseca*, 480 U.S. at 442-443, 446-450.

Or, the *Gardner* canon might operate to supercede *Chevron* deference at *Chevron*'s step two, as in *DeBartolo Corp. v. Florida Gulf Coast Building and Construction Trades Council*, 485 U.S. 568, 574-578 (1988). As between substantive statutes themselves, the more narrow rule of construction, here the *Gardner* rule, should supercede the more general. *See Traynor v. Turnage*, 485 U.S. 535, 547-48 (1988). Only this Court is in the position to resolve the conflict in this case between these two canons of construction, and thereby clarify the law for all veterans nationwide on this important matter.[22]

[22] The Court of Appeals' alternative ground for rejecting the veterans' statutory argument, that it would lead to "absurd re-

III. UNDER THE ADMINISTRATIVE PROCEDURE ACT, AN AGENCY DECISION BASED SOLELY ON FACTS AND SCIENTISTS' CONCLUSORY OPINIONS, BUT FAILING TO CONSIDER RELEVANT SCIENTIFIC PRINCIPLES AND EXPLAIN REASONING FROM THE FACTS FOUND TO THE OPINION REACHED, IS "ARBITRARY AND CAPRICIOUS" UNDER *BURLINGTON TRUCK LINES* AND *BALTIMORE GAS*

For an agency's scientific determination to avoid being "arbitrary and capricious" under the APA, it must be based on more than facts and conclusory expert opinions; it must also have considered the relevant scientific principles and explained how the agency reasoned from the facts found to the conclusion reached. These requirements flow directly from this Court's decisions. *In Baltimore Gas*, 462 U.S. at 105-106, the Court recognized that the usual criteria that govern analysis under the "arbitrary and capricious" clause of 5 U.S.C. § 706(2)(A) also govern review of scientific decision-making.

A. Failure To Consider Relevant Factors

Thus, the Court "is to determine whether the [agency] has considered the relevant factors. . . ." *Baltimore Gas*, 462 U.S. at 105; accord, *Motor Vehicles Manufacturers*, 463 at 43 (agency may not "fail[] to consider an important aspect of the problem, ..."). What are the

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sults", App. 14, 17a, n.13, and 17a-18a, hinges entirely on the court's "[*a*]*ssuming the accuracy* of the Secretary's conclusion that a scientifically valid Agent Orange study was infeasible. . . ." (Emphasis added) App. 18a. Thus, even the Court of Appeals seems to concede that unless the Secretary's conclusion that it was impossible to conduct a scientifically valid study were "accurate" (or at least had a rational basis), there would be no logical ground for finding it "absurd" to read the Act as requiring the study.

The veterans' last reason for granting the petition shows that the Secretary had no rational, or lawful, basis for his conclusion that it was impossible to do a valid study. Accordingly, the Court of Appeals' finding of "absurd results" was unfounded, and the study cancellation not only violated the Act, but was also illegally "arbitrary and capricious."

"relevant factors" must necessarily be determined by reference to the particular decision being challenged.

Here, the decision is the Secretary's conclusion that the degree of risk of misclassification makes it impossible to do a scientifically valid epidemiological study with military records alone, unless their accuracy is independently verified. Given the nature of this decision, it would be essential for the Secretary (or his scientists) to have considered both what was the degree of risk of misclassification to which the study was subject, and what are the scientific principles [23] for determining when risk of misclassification becomes so great that it not only makes it harder to detect true adverse health effects, but renders the study scientifically invalid.

The first element is not in dispute because the Subpanel made findings as to the degree of risk of misclassification that a military records study would present. First, it identified the two principal problems with the military records which prevented their being able to verify which individuals had been exposed to herbicides containing dioxin and which had not: (i) unit dispersion—the pilot study on which the subpanel relied showed that "[o]n a substantial number of days," some soldiers in combat units eligible for the study were dispersed for some time period from the main unit, but the military records failed to report which individuals within the unit were located where; [24] and (ii) incomplete spray records—although

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[23] In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786, 2797 (1993), this Court recognized that it was so important that scientists disclose the scientific principles which underlay their opinions that it established that "[t]he focus [of admissibility determinations under Fed. R. Evid. 702] must be solely on [scientific] principles and methodology, not on the conclusions they generate." Similarly, F.R. Civ. P. 26(a)(2)(B), as amended in 1993, generally requires disclosure to other parties before trial not only of "all opinions" to which any retained experts will testify, but also "the basis and reasons therefor."

[24] The main units that the pilot study analyzed were companies, each with approximately 225 soldiers. See Declaration of Richard Christian, ¶ 11, p. 6, ¶ 16, p. 11, ¶ 19-26, pp. 13-19. The military

Ranch Hand spray missions (from fixed wing aircraft) and some perimeter spray missions were recorded, "an unknown, but apparently large proportion of firebase perimeter spray operations were never recorded." [25] Jt. App. 45. The Subpanel observed that these problems would inevitably cause some study subjects to be misclassified as to exposure status. Jt. App. 45A.

Then, the Subpanel found the degree of risk posed by these two problems to be as follows: "it appears that considerable misclassification of the individual's exposure status is possible; *i.e.*, we found no way, based on military records, to verify an individual's exposure to herbicide or dioxin." App. 45. "The combined effect of [the] two sources of misclassification is unclear . . . undoubtedly they would seriously bias measures of effect toward the null and greatly reduce study power." App. 46. (That is, the misclassification would seriously bias the study toward not detecting true adverse health effects and would reduce its ability to find such effects.)

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records contained information as to the daily location and size of every subunit that was dispersed from the company headquarters, "no matter how small." See Christian Declaration ¶¶ 24-26, pp. 17-19. Thus, for every company the pilot study reviewed, the Subpanel could have determined the size of the subunit (e.g., squad: 4 or 5 soldiers, or platoon: 40 soldiers) that was dispersed from the company headquarters, and therefore whether the potential misclassification affected a large portion of veterans or only a very small proportion. However, the record shows that the Subpanel totally failed to consider this vital factor bearing on the relative severity of the misclassification risk and therefore the scientific validity of the study. Petitioners believe that the Christian Declaration is admissible per footnote 9. The Clerk's Office has a copy.

[25] The military estimated that 98% of all Agent Orange sprayed in Vietnam was sprayed by the Ranch Hand fixed wing aircraft, for which there were complete records of spray location, date and quantity, and only 2% was devoted to perimeter spraying. NAS Report at 90, 94 and 97. Two systems of computerized tapes together were able to account for approximately 19.2 million gallons of the estimated total 20 million gallons of herbicides sprayed in Vietnam. NAS Report 97-98.

As to the second element, however, neither the Secretary nor any experts on whom he relied, explained any scientific principles that they may have used to determine that the degree of misclassification risk the Subpanel found was so high that it exceeded the maximum risk permitted for a study to be scientifically valid. They neither discussed the five factors for making this assessment identified by a senior, full professor of epidemiology at Columbia University's School of Public Health,[26] nor proffered any other scientific standards for making this critical determination.

Instead, the Subpanel relied solely on its "feelings" for its conclusion that the risk of misclassification was so great that it was impossible to do a scientifically valid study with military records, unless their accuracy were independently verified. Its entire justification consisted of the following: "*the Subpanel felt that an additional method to verify exposure is required prior to the conduct of a scientifically valid epidemiological study.*" (Emphasis added) Jt. App. 46.

The Court of Appeals found that the Secretary's "conclusion that an exposure verification method was necessary" was based not only on the Subpanel's "feelings", but also on three specific opinions and findings by other scientists. App. 2a4-25a, n.16. However, the record does not support the appeals court's findings.

First, the Court of Appeals said that "OTA had similarly concluded that because of misclassification problems, an independent method of exposure assessment or some means of verifying the records-based exposure estimates was needed." App. 24a-25a, n.16. In fact, the administrative record shows that OTA *never* endorsed

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[26] Dr. Zena A. Stein had explained in her affidavit that for such a study to be valid, it would need to "meet a minimum threshold of probability and comparability as to . . . five conditions." Jt. App. 302-303. These were summarized by the Court of Appeals as involving "the fact of exposure, amount and duration of exposure, and other personal characteristics and influences that might affect individuals' health." App. 26a.

the Subpanel's opinion as to the unreliability of military records.[27] Rather, OTA favored independent study of blood dioxin levels for the entirely different purpose of verifying whether, as the military records suggested, even the "likely exposed" cohorts had not been heavily exposed to herbicides. Jt. App. 70. OTA ultimately opposed conducting the study not because of any concern over misclassification but because it believed a study would not be useful where "a large percentage of ground troops were [not] heavily exposed to Agent Orange." Jt. App. 78.

Second, the Circuit Court said that "the TCDD study . . . confirmed that military records did not give reliable estimates of exposure to Agent Orange among ground troops." App. 24a-25a, n.16. But the record reveals that the blood study merely failed to verify that the military records were accurate in distinguishing "likely exposed" from "likely not exposed" cohorts. Jt. App. 288a-289. It never found the converse: that the military records were unreliable. Indeed, the court's conclusion is undermined by its own admission of "[t]he fact that the TCDD study left open the possibility that military records might accurately identify exposed veterans at low levels of exposure." App. 24a.

Third, the Court of Appeals asserted that the blood study "confirmed . . . that most ground troops had never faced meaningful exposure to Agent Orange or other herbicides." App. 24a-25a, n.16. In fact, the CDC blood study found that most Army ground troops had not had

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[27] To the contrary, OTA's opinion was that the TCDD study (the blood study) "strongly validate[d]" the military records' accuracy in that it confirmed the military records' showing that the vast majority of ground combat veterans had not been heavily exposed to herbicides. Jt. App. 71. OTA's view was that: "*It remains possible that military records do allow a valid estimate of exposure*, but that the range of exposure in this population is too small to permit evaluation [by the blood study due to removal of dioxin from the body over the 20 years since exposure.]" (Emphasis added) *Id.*

"heavy exposure", but never addressed whether the amount received was "meaningful." Jt. App. 288A-289.[28] Moreover, even if the blood study had found that most troops had not had "meaningful" exposure, that would not have supported the Subpanel's conclusion that misclassification was so great that the military records could not be relied on to distinguish cohorts who had been relatively more exposed from those relatively less exposed. As OTA averred, the military records might be reliable, but the overall level of exposure may have been too low for differences to be detected in the blood 20 years later. See Jt. App. 71-72.

Rather, any opinion as to "meaningfulness" of exposure, at most, would have been a separate potential basis on which the Secretary might have opposed a study on policy grounds as wasteful, but not as scientifically invalid. However, the Secretary never relied on OTA's opinion as to the purported lack of "meaningful" exposure as a basis for canceling the study. If he had, it would have been illegal because Congress in Pub. L. 96-151 did not make its mandate to conduct an exposure study contingent on veterans having been "heavily exposed" to herbicides; instead, it wanted to find out if there were any adverse health effects from whatever level of exposure the veterans had actually experienced.

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[28] While OTA, not CDC, opined that the blood study "confirms a low probability for meaningful exposures for Vietnam veterans as a group", Jt. App. 76, it never cited any scientific evidence in support of its opinion that the levels to which such troops were exposed were not "meaningful." If OTA meant that the levels of exposure to dioxin were too low to cause adverse health effects, that would conflict with CDC's findings that it is not possible "to define objectively 'meaningful' exposure", Jt. App. 102, and that "levels of TCDD in man at which adverse health effects become manifest are not known." Jt. App. 134B. If the Secretary had relied on OTA's opinion in this regard as a ground for canceling the study, there would have been a "genuine issue of material fact" under F.R. Civ. P. 56 as to the "meaningfulness" of the actual exposures, making summary judgment inappropriate.

In short, the Secretary failed to consider the relevant factor of scientific principles, and had no other adequate support for his conclusion that military records alone could not produce a scientifically valid study.[29] His cancellation was "arbitrary and capricious" on this ground alone.

B. Failure To Explain Rational Connection Between Facts Found And Conclusion Reached

In *Burlington Truck Lines*, 371 U.S. at 168, the Court established that for an agency decision to avoid being "arbitrary and capricious" it must also "articulate [a] rational connection between the facts found and the choice made. . . ." Accord, *Baltimore Gas*, 462 U.S. at 105. Here, to the contrary, the Secretary gave no explanation for why he concluded that the misclassification risk would preclude a scientifically valid study, except for the Subpanel's "feelings."

As the Court said in *Burlington*: "There [is] no analysis here to justify the choice made, no indication of the basis on which the [agency] exercised its expert discretion. We are not prepared to and the Administrative Procedure Act will not permit us to accept such adjudicatory practice," 371 U.S. at 167. Likewise as in *Burlington*, the agency here "should have been particularly careful," 371 U.S. at 172, in making its decision because of the serious consequences for Vietnam veterans nationwide from concluding that it was impossible to do a valid study with military records.

To allow this one word—"feelings"—to suffice as an explanation would be to permit " '*expertise* . . . [to] become a monster which rules with no practical limits on its discretion.' " *Burlington Truck Lines*, 371 U.S. at 167, quoting *New York v. United States*, 342 U.S. 882, 884 (1951). (Emphasis in original). This would be a grave

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[29] Indeed, NAS concluded that misclassification risk would *not* make the study scientifically "invalid", but would only be "likely . . . to underestimate the effects if they existed." Jt. App. 287.

injustice to petitioners and hundreds of thousands of Vietnam veterans and their families nationwide. The veterans ask this Court to no more allow unexplained and unreasoned decision-making on matters of national import to go unchecked here than it did in *Burlington* and *Motor Vehicles*, 463 U.S. at 56-57. Too much is at stake for too many veterans.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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